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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,545	08/29/2001	Lloyd Wolfinbarger JR.	067949-5006-03	5273

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MORGAN LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20004

EXAMINER	
COMSTOCK, DAVID C	
ART UNIT	PAPER NUMBER
3733	
MAIL DATE	DELIVERY MODE
02/26/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/940,545	WOLFINBARGER ET AL.	
	Examiner	Art Unit	
	DAVID COMSTOCK	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33 and 34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

In view of the appeal brief filed on 19 November 2007, PROSECUTION IS HEREBY REOPENED. New or amended grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

Claim Rejections - 35 USC § 102 / 35 USC § 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 34 is rejected under 35 USC 102(e) as being anticipated by Boyce et al. (5,899,939), or alternatively, under 35 USC 103(a), as being obvious over Boyce et al.

Boyce et al. disclose a monolithic bone implant, i.e., whole bone or a portion of whole bone, 22, that is contacted with a liquid organic agent, e.g., glucose (see, e.g., Abstract; Fig. 2; col. 3, lines 30-35, col. 4, lines, 53-60; col. 5, line 6, 22-32). Glucose is one of the liquid organic stength-conserving agents specifically listed in Applicants'

specification (see, e.g., page 13 lines 8-10 and page 15, line 7). As such, it is rightly presumed to exhibit the same properties and characteristics, and would therefore be capable of penetrating and remaining in the bone. Furthermore, the glucose is considered to be capable of penetrating and remaining in bone because the reference explains that the bone has cavities, pores, apertures, perforations and channels for this purpose (col. 2, lines 10-16 and col. 4, lines 53-60). Moreover, the reference discloses that the listed agents, including glucose, can be incorporated by various methods including coating, immersion, saturation, packing, etc. (col. 5, lines 24-32). Finally, Boyce teaches that the useful substances such as glucose can be incorporated into the implant at any stage of its assembly and that the implant of the invention can be lyophilized or freeze-dried (see col. 5, lines 24-28 and col. 6, Example 1). It is noted that the term lyophilized simply means freeze-dried (see Applicants' specification, page 19, lines 21 and 22). Therefore, it is apparent that all of the elements in claim 34 are disclosed by Boyce et al. It is noted that it is neither necessary nor practical for the Boyce et al. reference to explicitly recite discrete examples showing every possible combination and permutation of useful substances and steps of the invention. It should be sufficient that it discloses the substance and specifically states that it can be incorporated into the implant at any stage. Even if the position (which Examiner maintains is unreasonable) were taken that a discrete, specific example showing the use of glucose is necessary for anticipation, it still would have been obvious to a person of ordinary skill in the art to have incorporated the glucose and lyophilized the implant, both because of the explicit teaching that the glucose can be incorporated to provide

biocidal/biostatic properties and make the implant medically/surgically more useful (see col. 4, lines 53-60 and col. 5, line 5) and because the reference explicitly says the substances can be added at any stage (see col. 5, lines 24-32).

The following comments are noted regarding the meaning of monolithic with respect to Boyce et al. A layer of bone 22 is monolithic because it is a whole bone or portion of a whole bone (as opposed to being, for example, morselized, pulverized or powdered). Because Applicants do not use a closed transition such as "consisting of" in the claims, the presence of any additional layers in Boyce et al. is irrelevant, since the additional structure has not been precluded by closed terminology. It is noted that even if the claims were amended to recite closed terminology, Boyce et al. encompasses an invention not having additional layers. Examiner acknowledges that the focus of Boyce et al. is directed to layered implants; indeed, the claims are directed solely to layered embodiments. However, Boyce et al. also explicitly recites that any additional layers that may be present are optional. If they are optional, they do not need to be there in all cases, and the reference, in such cases, encompasses only a bone layer. For example, see:

Abstract: “A bone derived implant is provided which is made up of **one** ***or*** more layers of fully mineralized or partially demineralized cortical bone and, ***optionally***, one or more layers of some other material." (Examiner's emphasis)

Col. 3, lines 30-35: “The bone-derived implant **can** include layers of varying thicknesses, e.g., the compression strength-imparting layer**(s)** can be considerably

thicker or thinner than **any optional** layer**(s)** that **may** be present." (Examiner's emphasis)

The scope of the reference encompasses a single layer bone implant, and in any event, where additional layers are present, they are not precluded by the claims. Therefore, layer of bone 22 is monolithic and anticipates or renders obvious the claim language, as set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boyce et al. (5,899,939) in view of Morse (5,333,626).

Boyce et al. (either alone, or as modified in the 102/103 rejection set forth above) disclose the claimed invention except for explicitly disclosing packaging of the implant. Morse discloses a similar invention that is packaged to preserve sterility and biologic potential in the implant and to avoid contamination and infection in the patient (see Fig. 1 and col. 1, lines 6-18; col. 2, lines 21-26; col. 3, lines 10-12, 21, 31-50, 57-61; col. 4, lines 8-12; col. 5, lines 57-65; col. 6, lines 5-25 and 43-46; and col. 7, lines 40-47). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the bone implant as disclosed by Boyce et al. with packaging, in

view of Morse, in order to preserve sterility and biologic potential of the bone implant and to avoid contamination and infection in the patient. With regard to the amount of the agent used, it would have been further obvious to provide the liquid organic agent in any amount or in any of numerous ranges of amounts, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Moreover, as previously noted, Boyce et al. specifically teach that "[t]he amounts of medically/surgically useful substances utilized can vary widely with optimum levels being readily determined in a specific case by routine experimentation." (See Boyce et al., col. 5, lines 29-32.)

Response to Arguments

Applicant's arguments in the Appeal Brief filed 19 November 2007 have been fully considered but are moot in view of the new or amended grounds of rejection set forth above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Comstock whose telephone number is (571) 272-4710 (a detailed message should be left if Examiner is unavailable). If attempts to reach the Examiner by telephone or voicemail are unsuccessful, the examiner's

supervisor, Eduardo Robert, can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/DC/

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733